

### **REMARKS**

Reconsideration and withdrawal of the rejections set forth in the Office action dated May 9, 2002 are respectfully requested.

Attached is a separate page captioned **"Version with Markings to Show Changes Made"** with a marked-up version of the claims to show the changes made.

#### **I. Amendments**

The specification has been amended to correct an obvious typographical error.

Claims 1, 6, 8, and 19-25 stand cancelled.

Claims 26, 30, 34, 38, and 42 are amended to clarify that the composition comprises flaxseed oil and that the composition has specified linoleic fatty acid (n-6, 18:2) to  $\alpha$ -linolenic fatty acid (n-3, 18:3) weight ratios.

Claims 42-45 are amended to recite a "food". Support for this amendment can be found on page 5, lines 4-6 and 17-20.

By these amendments, no new subject matter has been added.

#### **II. Rejection under 35 U.S.C. §112, First Paragraph**

Claims 27, 35, 39 and 43 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the invention without undue experimentation. Specifically, the Examiner alleges that rapeseed oil was not disclosed in the original specification. Applicants respectfully traverse the rejection for the following reason.

Applicants direct the Examiner to page 7, line 3 where flaxseed, "repseed" and perilla oils were ground. "Repseed" is an obvious typographical error for "rapeseed". One skilled in the art would have understood that the inventor was in possession of the invention comprising "rapeseed oil".

In light of the above, Applicants submit that the present claims satisfy the enablement requirement of §112, first paragraph and respectfully request that the rejection be withdrawn.

### III. Rejection under 35 U.S.C. §112, second paragraph

Claims 1, 6, 8 and 19-45 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Applicants have cancelled claims 1, 6, 8 and 19-25 and thus only address those items pertaining to the remaining pending claims. The Examiner had three specific objections, which are set forth and addressed below.

1. Rejection of Claims 42-45: The Examiner objected the language "foodstuff" as allegedly vague and indefinite. Applicants have amended the claims to recite a "food". Applicants further direct the Examiner to pages 5, lines 4-6 and 17-20 for exemplary foods.

2. Rejection of Claims 26-45: The Examiner objected the language of claims 26-45 as allegedly confusing. Specifically, the Examiner questions whether the composition comprises flaxseed oil, linoleic fatty acid, and linolenic fatty acid. Applicants have amended claims 26, 30, 34, 38, and 42 to delete the language "wherein the composition comprises linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (N-3, 18:3)" to clarify that the composition comprises flaxseed oil and further that the linoleic and  $\alpha$ -linolenic fatty acids are present in specified weight ratios and are at least in part derived from the flaxseed oil.

3. Rejection of claim 34: The Examiner objected to the term "edible oil" in claim 34 as allegedly vague and indefinite. Applicants submit that the term "edible oil" is widely known in the art. In support, Applicants submit a treatise from the United States Food and Drug Administration documenting the labeling requirements of edible oils. Accordingly, Applicants submit that the term "edible oil" is clear to one skilled in the art.

Applicants respectfully submit that claims 26-45 are in full compliance with the requirements of 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph are respectfully requested.

IV. Rejections under 35 U.S.C. §102

Claims 1, 8 and 19 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Horrobin (European Patent No. 211 502).

This rejection is obviated by way of Applicants' amendments. Withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

V. Rejections under 35 U.S.C. §103

Claims 1, 6, 8 and 19-25 were rejected under 35 U.S.C. §103 as allegedly obvious over Yehuda (U.S. Patent No. 5,416,114) in view of Igarashi (U.S. Patent No. 6,159,507).

Claims 1, 6, 8 and 19-25 were rejected under 35 U.S.C. §103 as allegedly obvious over Harumi *et al.* (Japanese Patent No. 61-85143) in view of Igarashi.

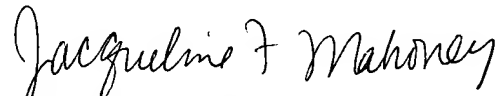
These rejections are obviated by way of Applicants' amendments. Withdrawal of the rejections under 35 U.S.C. §103 is respectfully requested.

VI. Conclusion

In view of the foregoing, Applicants submit that the claims pending in the application comply with the requirements of 35 U.S.C. §112 and patentably defines over the cited art. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,



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Date: August 9, 2002

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Application No. 09/499,693

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

In the specification:

On page 7, please replace the paragraph starting on line 3 with the following:

Flaxseed, [repseed[rapeseed and perilla oils were ground, subjected to fatty acid analysis, mixed together to prepare higher unsaturated fatty acid compositions so that the weight ratio of linoleic acid to  $\alpha$ -linolenic acid would be 2, 7.5, 10 and 16. There specimens were given to rats by mixing in their feed so that the content of the higher unsaturated fatty acid composition will be 3 to 5% with respect to the feed.

In the claims:

26. (Amended) An unsaturated fatty acid composition comprising flaxseed oil, [wherein the composition comprises linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (N-3, 18:3),] wherein the weight ratio of [said] linoleic fatty acid (n-6, 18:2) to [said]  $\alpha$ -linolenic fatty (n-3, 18:3) acid in said composition is 0.05-7.5.

30. (Amended) A capsule comprising an unsaturated fatty acid composition comprising flaxseed oil, [wherein the composition comprises linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18:3),] wherein the weight ratio of [said] linoleic fatty acid n-6, 18:2 to [said]  $\alpha$ -linolenic fatty acid (n-3, 18:3) in said composition is 0.05-7.5.

34. (Amended) An edible oil comprising flaxseed oil, [wherein the oil comprises linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18:3),] wherein the weight ratio of [said] linoleic fatty acid (n-6, 18:2) to [said]  $\alpha$ -linolenic fatty acid (n-3, 18:3) in said oil is 0.05-7.5.

38. (Amended) A dietary supplement comprising flaxseed oil, [wherein the supplement comprises linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18:3),] wherein the weight ratio of [said] linoleic fatty acid (n-6, 18:2) to [said]  $\alpha$ -linolenic fatty acid (n-3, 18:3) in said supplement is 0.05-7.5.

42. (Amended) A [foodstuff]food comprising flaxseed oil, [wherein the foodstuff comprises linoleic fatty acid (n-6, 18:2) and  $\alpha$ -linolenic fatty acid (n-3, 18:3),] wherein the weight ratio of [said] linoleic fatty acid (n-6, 18:2) to [said]  $\alpha$ -linolenic fatty acid (n-3, 18:3) in said foodstuff is 0.05-7.5.

43. (Amended) The [foodstuff]food of claim 42, further comprising rapeseed oil and perilla oil.

44. (Amended) The [foodstuff]food of claim 42, wherein the weight ratio of said linoleic fatty acid to said  $\alpha$ -linolenic fatty acid in said [foodstuff]food is 0.05-2.0.

45. (Amended) The [foodstuff]food of claim 43, wherein the weight ratio of said linoleic fatty acid to said  $\alpha$ -linolenic fatty acid in said [supplement]food is 0.05-2.0.

U.S. Food and Drug Administration**Edible Oils**

Olive oil is the edible oil expressed from the sound, mature fruit of the olive tree. Refined or extracted oil is not entitled to the unqualified name "olive oil."

Other vegetable oils should be labeled by their common or usual names, such as cottonseed, sunflower, peanut, and sesame. Mixtures of edible oils should be labeled to show all the oils present and the names should be listed on the labels in the descending order of predominance in the product. Terms such as "vegetable oil" or "animal shortening" are permitted, provided that the source of each oil or fat used in the product is disclosed" (21 CFR 101.4(b)(14)). Pictures, designs, or statements on the labeling must not be misleading as to the kind or amount of oils present or as to their origin.

Cod liver oil is a drug as well as a food since it is recognized in the United States Pharmacopeia (USP). Its value as a food whether intended for human or animal use depends mainly on its vitamin D content. Articles offered for entry as cod liver oil must comply with the identity standard prescribed by the USP and conform to the other specifications set forth in that official compendium.

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